

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE**

**2nd VIRTUAL JOINT MEETING
of the
BOARD OF SCIENTIFIC ADVISORS AND
NATIONAL CANCER ADVISORY BOARD**

**Summary of Meeting
June 15, 2020**

**Virtual Meeting
National Cancer Institute
National Institutes of Health
Bethesda, Maryland**

**BOARD OF SCIENTIFIC ADVISORS and
NATIONAL CANCER ADVISORY BOARD JOINT MEETING
BETHESDA, MARYLAND
Summary of Meeting
15 June 2020**

The Board of Scientific Advisors (BSA) of the National Cancer Institute (NCI) and the National Cancer Advisory Board (NCAB) convened for the 2nd Virtual Joint Meeting on 15 June 2020. The meeting was open to the public on Monday, 15 June 2020, from 10:00 a.m. to 4:50 p.m. and closed to the public on Monday, 15 June 2020, from 5:00 p.m. to 5:47 p.m. The NCAB Chair, Dr. Elizabeth M. Jaffee, Deputy Director, The Sidney Kimmel Comprehensive Cancer Center, Co-Director, Skip Viragh Center for Pancreas Cancer, The Dana and Albert “Cubby” Broccoli Professor of Oncology, Johns Hopkins University, and BSA Chair, Dr. Dafna Bar-Sagi, Saul J. Farber Professor, Department of Biochemistry and Molecular Pharmacology and Medicine, Executive Vice President and Vice Dean for Science, and Chief Scientific Officer, New York University (NYU) Langone Health, NYU School of Medicine, presided during the open session. Dr. Jaffee presided during the closed session. In the open session, the BSA considered new requests for applications (RFAs), Cooperative Agreements (Coop. Agr.), requests for proposals (RFPs), and program announcements with special receipt, referral, and/or review (PARs) of new and re-issue concepts presented by NCI Program staff.

BSA Members

Dr. Dafna Bar-Sagi (Chair)
Dr. Kenneth C. Anderson
Dr. Michael John Becich
Dr. Mary C. Beckerle (absent)
Dr. Melissa L. Bondy
Dr. Otis W. Brawley
Dr. Graham A. Colditz
Dr. Christopher M. Counter (absent)
Dr. Carol E. Ferrans
Dr. Keith T. Flaherty
Dr. Karen E. Knudsen
Dr. James V. Lacey, Jr.
Dr. Michelle M. Le Beau
Dr. Sylvia Katina Plevritis
Dr. W. Kimryn Rathmell
Dr. Leslie L. Robison
Dr. Martine F. (Sheer) Roussel
Dr. Robert D. Schreiber
Dr. Victoria L. Seewaldt
Dr. Kevin M. Shannon
Dr. David Sidransky
Dr. Ian M. Thompson, Jr.
Dr. David A. Tuveson
Dr. Robert H. Vonderheide
Dr. Eileen P. White
Dr. Cheryl L. Willman

NCAB Members

Dr. Elizabeth M. Jaffee (Chair)
Dr. Peter C. Adamson (absent)
Dr. Francis Ali-Osman
Dr. Anna D. Barker
Dr. Deborah Watkins Bruner
Dr. Yuan Chang
Dr. Howard J. Fingert
Mr. Lawrence O. Gostin (absent)
Dr. Andrea A. Hayes-Jordan
Dr. Scott W. Hiebert
Dr. Timothy J. Ley
Dr. Electra D. Paskett
Dr. Nancy J. Raab-Traub
Dr. Margaret R. Spitz
Dr. Susan Thomas Vadaparampil
Dr. Max S. Wicha

Alternate Ex Officio NCAB Members

Dr. Robert T. Anderson, DOE (absent)	Dr. Craig D. Shriver, DoD
Dr. Michael A. Babich, CPSC	Dr. Kerry Souza, NIOSH (absent)
Dr. Michael Kelley, VA (absent)	Dr. Lawrence A. Tabak, NIH (absent)
Dr. Aubrey Miller, NIEHS	Dr. Aaron Tustin, OSHA
Dr. Richard Pazdur, FDA (absent)	

Members, Scientific Program Leaders, National Cancer Institute, NIH

Dr. Norman E. Sharpless, Director, National Cancer Institute
Dr. L. Michelle Bennett, Director, Center for Research Strategy
Dr. Oliver Bogler, Director, Center for Cancer Training
Dr. Stephen J. Chanock, Director, Division of Cancer Epidemiology and Genetics
Dr. Henry P. Ciolino, Director, Office of Cancer Centers
Dr. Robert Croyle, Director, Division of Cancer Control and Population Sciences
Dr. William Dahut, Scientific Director for Clinical Research, Center for Cancer Research
Dr. James H. Doroshow, Deputy Director for Clinical and Translational Research and Director, Division of Cancer Treatment and Diagnosis
Dr. Dan Gallahan, Director, Division of Cancer Biology
Mr. Peter Garrett, Director, Office of Communications and Public Liaison
Dr. Satish Gopal, Director, Center for Global Health
Dr. Paulette S. Gray, Director, Division of Extramural Activities
Dr. Ed Harlow, Special Advisor to the NCI Director
Dr. Toby T. Hecht, Deputy Director, Division of Cancer Treatment and Diagnosis
Dr. Sara Hook, Director, Office of Scientific Operations, NCI Campus at Frederick
Dr. Tony Kerlavage, Director, Center for Biomedical Informatics and Information Technology
Dr. Douglas R. Lowy, Principal Deputy Director, National Cancer Institute
Dr. Glenn Merlino, Scientific Director for Basic Research, Center for Cancer Research
Dr. Tom Misteli, Director, Center for Cancer Research
Dr. Margaret Mooney, Associate Director, Cancer Therapy Evaluation Program
Dr. Henry Rodriguez, Acting Deputy Director, Center for Strategic Scientific Initiatives
Mr. Jeff Shilling, Chief Information Officer and Chief of Infrastructure and Information Technology Services Branch, Center for Biomedical Informatics and Information Technology
Ms. Donna Siegle, Executive Officer and Deputy Director for Management, Office of the Director
Dr. Dinah Singer, Deputy Director, Science Strategy and Development
Dr. Sanya Springfield, Director, Center to Reduce Cancer Health Disparities
Dr. Louis M. Staudt, Director, Center for Cancer Genomics
Mr. Michael Weingarten, Director, Small Business Innovation Research and Small Business Technology Transfer Programs
Dr. Deborah M. Winn, Acting Director, Division of Cancer Prevention
Dr. Robert Yarchoan, Director, Office of HIV and AIDS Malignancy
Dr. Maureen Johnson, Executive Secretary, Office of the Director

Liaison Representatives

Ms. Carolyn Aldige, Prevent Cancer Foundation
Dr. Carol Brown, Society of Gynecologic Oncologists
Dr. Margaret Foti, American Association for Cancer Research
Dr. Leo Giambarresi, American Urological Association
Dr. Francis Giardiello, American Gastroenterological Association

Dr. Mary Gullatte, Oncology Nursing Society
Dr. Ruth Hoffman, American Childhood Cancer Organization
Dr. Steven L. Klein, National Science Foundation
Ms. Laura Levit, American Society of Clinical Oncology
Ms. Maria Lopez, Kidney Cancer Association
Dr. W. Marston Linehan, Society of Urologic Oncology
Ms. Margo Michaels, Education Network to Advance Cancer Clinical Trials
Dr. Patricia Mullan, American Association for Cancer Education, Inc.
Ms. Shelly Fuld Nasso, National Cancer Institute, Council of Research Advocates
Ms. Nancy O'Reilly, American College of Obstetricians and Gynecologists
Ms. Leah Ralph, Association of Community Cancer Centers
Ms. Christy Schmidt, American Cancer Society
Ms. Susan Silver, National Coalition for Cancer Survivorship
Ms. Barbara Duffy Stewart, Association of American Cancer Institutes
Dr. Johannes Vieweg, American Urological Association
Dr. Pamela A. Wilcox, American College of Radiology
COL. (Ret.) James E. Williams, Jr., Intercultural Cancer Council

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MONDAY, 15 JUNE 2020

I. CALL TO ORDER AND OPENING REMARKS—DRS. ELIZABETH M. JAFFEE AND DAFNA BAR-SAGI

Dr. Elizabeth M. Jaffee called to order the 2nd Virtual Joint Board of Scientific Advisors (BSA) and National Cancer Advisory Board (NCAB) meeting. Dr. Jaffee welcomed members of the Boards, *ex officio* members, liaison representatives, staff, and guests. Members of the public were welcomed and invited to submit to Dr. Paulette S. Gray, Director, Division of Extramural Activities (DEA), National Cancer Institute (NCI), in writing and within 10 days, any comments regarding items discussed during the meeting. Dr. Jaffee reviewed the confidentiality and conflict-of-interest practices required of Board members in their deliberations.

Motion. A motion to accept the minutes of the 11 February 2020 NCAB Meeting was approved unanimously.

Motion. A motion to accept the minutes of the 9 April 2020 Joint Meeting of the BSA and the NCAB was approved unanimously.

Motion. A motion to accept the minutes of the 12 May 2020 BSA Meeting was approved unanimously.

Dr. Jaffee called Board members' attention to the future meeting dates listed on the agenda.

II. NCI DIRECTOR'S REPORT—DR. NORMAN E. SHARPLESS

Dr. Norman E. Sharpless, Director, NCI, welcomed members of both the BSA and NCAB to the 2nd Virtual Joint Meeting of these Boards. Dr. Sharpless reminded the BSA and NCAB members that the fiscal year (FY) 2021 NIH/NCI budget appropriations process is different from prior years. Congress has addressed legislation concerning the coronavirus disease 2019 (COVID-19) pandemic and is working on a fifth emergency appropriations bill. He noted that Ms. M.K. Holohan, Director, Office of Government and Congressional Relations (OGCR), will provide further details on the NCI FY 2021 budget later in the meeting. Dr. Sharpless provided an update on NCI's COVID-19 activities, the impact of the COVID-19 pandemic on cancer care, and leadership changes.

NCI COVID-19 Activities. Dr. Sharpless assured the Boards that NCI's primary focus remains the health and safety of people with cancer, health care providers, and the NCI staff and grantees. He conveyed that the NCI is honored to also contribute its expertise and infrastructure to the critical research related to COVID-19, a detailed list of which can be accessed from the NCI website. In the fourth COVID-19 supplement—the Paycheck Protection Program and Health Care Enhancement Act—Congress allotted the NCI a supplemental appropriation of \$306 million (M) for research on COVID-19 serology and related technologies. This funding is primarily an outcome of NCI's efforts to convert the Frederick National Laboratory for Cancer Research (FNLCR) human papillomavirus (HPV) Serology Laboratory to working on SARS-CoV-2 serology. The FNLCR collected samples and reagents and worked with the Centers for Disease Control and Prevention (CDC) and the National Institute of Allergy and Infectious Diseases (NIAID) to develop an enzyme-linked immunosorbent assay (ELISA)-based test. In addition, the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health requested FNLCR's assistance in performance evaluations of COVID-19 tests, which has resulted in a productive collaboration.

The NCI initiated two new COVID-19 efforts to meet the urgent need associated with the pandemic. On 12 May 2020, the Boards approved the NCI COVID-19 Serological Research Initiative. Subsequently, the NCI proposed establishing the Serological Sciences Network for COVID-19 Research (SeroNet) and published funding opportunity announcements (FOAs). Although the SeroNet will not be

solely focused on cancer, the NCI anticipates that the resulting studies also will benefit cancer patients. The NCI launched a cancer and COVID-19 natural history study, NCI COVID-19 in Cancer Patients Study (NCCAPS), to build a U.S. COVID-19 longitudinal cohort. Dr. Sharpless noted that further details of each of these new efforts will be provided later in the meeting.

Impact of the COVID-19 Pandemic on Cancer Care. Dr. Sharpless reported on the impact of the COVID-19 pandemic on long-term trends in cancer statistics. For decades, the United States has seen great progress in the national cancer mortality statistics, which the NCI and other federal agencies and private-sector groups supporting cancer research would not want to see weakened. The delayed diagnosis resulting from reduced screenings, follow-up, and visits to clinicians all have led to delayed treatments and increased mortality. The deferred care of elective procedures, such as postponed surgery, radiation, and chemotherapy, also have resulted in delayed treatments and increased mortality. In addition, reduced and/or non-standard care (e.g., neoadjuvant therapies) has led to reduced response and increased mortality. Underlying these factors is reduced access to care for the uninsured, underinsured, and underserved populations. Although redirecting some hospital operations was necessary to support the increased COVID-19 patient load, the NCI is interested in understanding how to resume care for cancer patients.

To estimate the potential effects of the COVID-19 pandemic on cancer mortality, the NCI Surveillance Research Program (SRP), Division of Cancer Control and Population Sciences (DCCPS), engaged the Cancer Intervention and Surveillance Modeling Network (CISNET). For two common cancers, breast and colon, with existing robust diagnosis and screening campaigns, the validated CISNET simulation models estimate 10,000 (i.e., 1%) additional cancer deaths over the next 10 years compared with a scenario without delayed screening and diagnosis. This analysis begins to assist the NCI to better understand the potential outcomes of the pandemic assuming a moderate disruption in these activities. The NCI will make every effort to minimize the adverse effects of the pandemic to protect patients.

Progress in Cancer Research. Dr. Sharpless highlighted recent progress in cancer research within the NCI Intramural Research Program (IRP) aimed at improving outcomes for liver and pancreatic cancers, neither of which has had significant progress in recent years. The NCI Center for Cancer Research (CCR) Liver Cancer Program, in the largest biomarker study to date for liver cancer, led by Dr. Xin Wei Wang, Deputy Chief, Laboratory of Human Carcinogenesis, reported in the 9 June 2020 issue of *Cell* that a “viral signature” of chronic exposure to 61 viruses, including hepatitis B and C viruses, can help improve liver cancer screening and early diagnosis. Using robust high-throughput screening techniques, CCR researchers evaluated a new blood test, VirScan, in blood samples from 173 patients with chronic liver disease. VirScan identified a signature of viral exposure that defines the early onset of hepatocellular carcinoma up to 10 years prior to a diagnosis.

Research shows that one in four people diagnosed with pancreatic cancer were first diagnosed with diabetes. The NCI in collaboration with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the Consortium for the Study of Chronic Pancreatitis, Diabetes, and Pancreatic Cancer (CPDPC) launched the New Onset Diabetes (NOD) Study. The study will recruit 10,000 participants between 50 and 85 years of age with newly diagnosed diabetes, establishing a NOD cohort and a biobank of clinically annotated biospecimens to facilitate identification of high-risk patients. To date, 439 patients have been enrolled across 12 trial sites in nine states. The NCI is partnering with the Pancreatic Cancer Action Network (PanCan) on this effort.

Leadership Updates. Dr. Sharpless announced that Dr. Philip E. Castle is now Director, Division of Cancer Prevention (DCP). and Dr. Emily S. Tonorezos has been selected as Director, Office of Cancer Survivorship (OCS). He expressed appreciation to Dr. Deborah M. Winn, who served as Acting Director, DCP, for the past year, and Dr. Deborah K. Mayer, who served as Interim Director, OCS, since the retirement of Dr. Julia Rowland in 2017. BSA and NCAB members were encouraged to visit NCI’s

blog, NCI Bottom Line, for up-to-date information about scientific research concepts and cancer research and training in the era of COVID-19.

Questions and Answers

Dr. Martine F. Roussel, St. Jude Children’s Research Endowed Chair in Molecular Oncogenesis, Department of Molecular Sciences, The University of Tennessee, Full Member, Department of Tumor Cell Biology, St. Jude Children’s Research Hospital, asked when the ELISA assay would be available to the cancer research community. Dr. Sharpless explained that a few patient-centered antibody-based assays are currently available at Quest Diagnostics and LabCorp and can be ordered without first seeing a physician. He noted that the health care community is unclear on how best to utilize this information, especially because the CDC guidance suggests not using antibody status in return-to-work decisions.

Dr. Francis Ali-Osman, Margaret Harris and David Silverman Distinguished Professor of Neuro-Oncology, Professor Emeritus of Neurosurgery, Duke University Medical Center, inquired about access to up-to-date information about the effects of delayed diagnosis on cancer patients as the disease is better understood. Dr. Sharpless clarified that the CISNET models are estimating additional mortality because of deferred care, delayed diagnosis, and screening—but not a change in the incidence of cancer. He further explained that COVID-19 is more of a threat to certain populations of cancer patients, which would far exceed this estimated 1-percent change in mortality in the next decade. The NCI supports the various public health measures soon to be implemented to limit the spread of COVID-19 in vulnerable populations and recognizes the need for hospitals to be innovative in developing plans to return delayed care to cancer patients. Dr. Jaffee, the NCAB Chair, suggested partnering with the NCI-Designated Cancer Centers (Cancer Centers) as one place to begin to better understand the challenges in resuming cancer patient care.

Dr. Deborah Watkins Bruner, Senior Vice President for Research, Robert W. Woodruff Professor in Nursing, Emory University, suggested investigating ways to systematically report social determinants of health in NCI National Clinical Trial Network (NCTN) clinical trials, such as implementing a standard form to capture these data in existing and new NCI initiatives and programs.

III. LEGISLATIVE REPORT—MS. M.K. HOLOHAN

Ms. Holohan reported on Congressional operations, COVID-19 funding, the FY 2021 appropriations process, and other legislative issues. She called attention to the detailed legislative report provided in the Board meeting materials and commented on the changes to Congressional procedures for hearings, with the most obvious being mask-wearing, remote hearings, and physical distancing. Although Congress is not structured for teleworking and voting remotely has unique challenges, on 15 May 2020, the House of Representatives, currently made up of 430 legislators, passed a rule that allows voting by proxy. This rule, which is in effect for 45 days, can be extended. Currently, 76 members of the House are voting by proxy. The 100-member Senate, with fewer members and typically smaller committees, can more easily practice physical distancing for in-person hearings and voting, and to date has not made allowances for remote voting.

Ms. Holohan detailed Congress’ rapid actions to address the economic impact of COVID-19 in March and April. Within just 50-days, Congress developed and passed four emergency spending packages totaling \$2.6 trillion: Phase 1, Coronavirus Preparedness and Response Supplemental Appropriations Act, enacted 3 March 2020; Phase 2, Families First Coronavirus Response Act, enacted 18 March 2020; Phase 3, Coronavirus Aid, Relief and Economic Security Act, enacted 27 March 2020; and, Phase 3b, Paycheck Protection Program and Health Care Enhancement Act, enacted 24 April 2020.

The NIH received funding in the Phase 1, 3, and 3b emergency supplemental COVID-19 funding bills, totaling \$3.6 billion (B). The NCI received \$306 M in the Phase 3b bill to develop, validate,

improve, and implement serological testing and associated technologies. Ms. Holohan noted that the COVID-19 appropriation is separate from the NCI regular appropriations.

Congress is currently are deliberating on a fifth emergency supplemental spending package, but the House and Senate have very differing perspectives on the scope and timing of the next aid package. On May 15, the House took the lead by passing a \$3 trillion Health and Economic Recovery Omnibus Economic Solution (HEROES) Act, which includes a \$4 B appropriation to the NIH to prevent, prepare for, and respond to coronavirus. The Senate has not introduced parallel legislation, and Majority Leader Mitch McConnell (R-KY) has indicated that they want to wait to see the effects of the earlier emergency spending packages before moving forward with a fifth supplemental in the \$1 trillion range.

Ms. Holohan emphasized that COVID-19 testing (e.g., diagnostic and antibody) remains a priority in Congress, and legislators have held several briefings and hearings on this topic and are requesting input from the U.S. Department of Health and Human Services (HHS), including the NCI. Congress also is continuing discussions on unemployment and the overall economic outlook since the start of the pandemic.

Ms. Holohan reminded the Boards that Dr. Sharpless testified at the 4 March 2020 FY 2021 House Appropriations Subcommittee on Health and Human Services, Education, and Related Agencies (Labor-HHS) budget hearing. The Senate Appropriations Labor-HHS Subcommittee budget hearing scheduled for March 26 was canceled due to COVID-19. She noted that it is not anticipated that FY2021 appropriations will be completed before the November elections. Congress is expected to pass a continuing resolution to keep the government funded for the first few months of FY2021.

Questions and Answers

Dr. Jaffee inquired on discussions in Congress concerning allocating funds to academic medical centers that could potentially experience significant financial deficits due to COVID-19, as well as support for early-career researchers who will be affected. Ms. Holohan replied that legislators are concerned about the impact on academic centers and noted that funds for NIH to address “restart” costs for research will likely be included in the fifth supplemental bill. She informed members that legislators also are discussing making permanent changes to the Centers for Medicare & Medicaid Services policy on telehealth in the proposed HEROES Act.

Questions and Answers

NCAB Chair Dr. Jaffee inquired on discussions in Congress concerning allocating funds to academic medical centers that could potentially experience significant financial deficits due to COVID-19, as well as support for early-career researchers who will be affected. Ms. Holohan replied that legislators are concerned about the impact on academic centers and noted that funds to address these issues likely will be included in the supplemental restart appropriations to the NIH. She added that legislators also are discussing making permanent changes to the Centers for Medicare & Medicaid Services policy on telehealth in the proposed HEROES Act.

IV. UPDATE: COVID-19 SEROLOGY AND IMMUNOLOGY CAPACITY BUILDING— DR. DOUGLAS R. LOWY

Dr. Douglas R. Lowy, Principal Deputy Director, NCI, reported on the progress in NCI’s COVID-19 serology efforts and the proposed SeroNet. He reminded the BSA and NCAB members that in January 2020, the NIAID, supported by the FNLCR, opened the Adaptive Coronavirus Treatment Trial (ACTT), a multicenter international trial evaluating remdesivir (Gilead Sciences) in hospitalized COVID-19 patients. Remdesivir, a known treatment for Ebola and Marburg viruses because of its function as an

RNA chain terminator, also inhibits replication of other RNA viruses, including coronaviruses. Currently, 60 to 70 percent of COVID-19 patients enrolled in the ACTT are in the United States, with the remainder participating internationally.

On 29 April 2020, Dr. Anthony Fauci, Director, NIAID, in a White House briefing from the Oval Office, reported that a trial endpoint had been reached and that remdesivir treatments improved the outcome for patients. In a preliminary account published in the 22 May 2020 issue of the *New England Journal of Medicine*, the ACTT study investigators reported that hospitalized COVID-19 patients treated with remdesivir (i.e., remdesivir group) were discharged from the hospital 31 percent sooner than patients not receiving the drug (i.e., placebo group). The 14-day mortality rate was 7.1 percent in the remdesivir group compared with 11.9 percent in the placebo group, but the results were not statistically significant (i.e., probability = 0.059) at the time of this report. These data continue to be evaluated, and the ACTT investigators are collecting data on the 28-day mortality rate.

The Boards were reminded that the NCI successfully converted part of the FNLCR HPV Serology Laboratory to SARS-CoV-2 Serology Laboratory, a collaborative research effort primarily with the NIAID, CDC, FDA, and Mount Sinai Hospital. The Cancer Centers also have been supporting this research. The short-term goals are to characterize the performance of different serologic assays and correlate the data with existing neutralization assays to better understand the possible cross-reactivity interactions from prior exposures to other coronaviruses. The long-term goals are to improve understanding of the implications of being seropositive in terms of resistance and duration and to participate in the cohort-oriented COVID-19 projects, such as the NCCAPS. Because of the increased interest from commercial laboratories in developing SARS-CoV-2 tests that the FDA considers devices, on 16 March 2020, the FDA permitted the sale of commercial laboratory-based and rapid lateral flow SARS-CoV-2 serology devices without an FDA performance assessment. The FDA clarified that only devices that measure viral RNA or viral protein are used to diagnose current SARS-CoV-2 infection and not these point-of-care serology devices. On 4 May 2020, the FDA granted emergency use authorization (EUA) to several commercial devices, but required all other manufacturers to submit EUA requests by 18 May 2020. On 4 June 2020, the FDA announced EUA for additional devices.

Dr. Lowy summarized the initial results of the 40 commercial serology devices evaluated by the FNLCR HPV Serology/SARS-CoV-2 Laboratory. Although the devices were assessed using both immunoglobulin G (IgG)-based and IgM-based antibody tests, Dr. Lowy emphasized focusing on IgG-based assays, which appear more stable than IgM-based tests. Among the 40 devices tested, the sensitivity, a detection of true positives, varied from 30 to 100 percent. The specificity, which does not detect false-positives, also varied across devices and was within 87 to 100 percent. The results have been sent to the FDA to help determine devices suitable for EUA, and some of these data are publicly available on the FDA website. Dr. Lowy projected that because of FDA's increased stringency, only devices with high sensitivity and high specificity will be available in the United States.

Dr. Lowy informed members that the importance of maintaining high specificity at low rates (less than 10%) of seroprevalence like that seen in most of the American population, except for first responders, other health care workers in epicenters of the COVID-19 pandemic, and vulnerable populations. He emphasized that even with a COVID-19 antibody test that has a 99-percent specificity, one out of five positive results (20%) likely will be false-positives in a population with a 5-percent seroprevalence rate. He also noted that a test with 95-percent specificity and a similar seroprevalence rate, one out of two positive results (50%) could potentially be false-positives.

Dr. Lowy stated that there are several key questions concerning seropositivity that currently are not well understood but are being addressed by this research, such as whether: 1) being antibody-positive is associated with active or prior SARS-CoV-2 infection and 2) these data can be used now for seroprevalence studies, as candidate polyclonal antibodies from convalescent sera and neutralizing monoclonal antibodies or for candidate SARS-CoV-2 vaccines. He noted that the NCI will launch a

Phase III COVID-19 vaccine trial in July 2020 and expressed appreciation to FNLCR HPV Serology/SARS-CoV-2 Laboratory and NCI collaborators across the federal government and industry for participating in this effort.

The NCI, in collaboration with the NIAID and CDC, will be establishing a new data resource, NCI COVID-19 SeroTracker, for strategic assessment of serology. NCI's Center for Biomedical Informatics and Information Technology (CBIIT) and FNLCR leadership teams, along with other collaborating subject-matter experts, currently are developing the requirements. NCI's SeroTracker will consist of a Serology Data Warehouse to serve as a research resource to the NCI/NIAID/CDC and the broader research community, with the Serology Tracking Dashboard containing a summary of global serology studies, assays, data and U.S. seroprevalence data. The aim is to develop a prototype in two stages, beginning with the dashboard component in the summer and the larger prototype in the fall of 2020.

Dr. Lowy explained that the NCI issued FOAs in support of the proposed SeroNet on 5 June 2020. The application due date is 22 July 2020. He described the components of the SeroNet as:

- **Special Serology Projects.** The FNLCR HPV/SARS-CoV-2 Serology Laboratory will conduct projects focusing on the implementation and validation of SARS-CoV-2 serology assays, building validation proficiency panels for assay development using SARS-CoV-2 patient samples, and producing assay standards.
- **Serological Capacity Building Centers (CBCs).** The CBCs will be geographically located across the country to develop, validate, and deploy serology tests in the local community. The CBCs also will acquire convalescent sera from recovered seropositive COVID-19 patients, conduct surveillance clinical trials in those patients, and pursue focused serological science on the acquired sera.
- **Serological Sciences Centers of Excellence.** The goals of the centers are to understand the mechanisms involved in the serological, humoral, and cellular immune responses to SARS-CoV-2 infection to inform development of novel serological tests; determine the serological correlates with disease pathogenesis and protection against future infection; and improve population-based models of outbreak and susceptibility through serology-focused studies. Each center will conduct two to three projects and include an administrative core and possibly a technical one.
- **Serological Sciences Projects.** The projects will share the goals of the Serological Sciences Centers of Excellence but will be supported by the Research Project Cooperative Agreement (U01) funding mechanism.
- **Network Coordinating Center.** The center's operations will be housed at the FNLCR and will provide program management across the network, coordinate data sharing and results, coordinate partnerships with national and international associates (e.g., CDC, FDA, World Health Organization, National Institute for Biological Standards and Control), and work closely with NCI staff.

The NCI also published a request for information (RFI) on research strategies for COVID-19 serology testing to incorporate feedback from the research community. The RFI responses will be reviewed and incorporated into the scope of the SeroNet; the FNLCR is the center of this "hub and spoke" model of collaboration. Dr. Lowy expressed appreciation to Dr. Dinah Singer, Deputy Director, Science Strategy and Development, NCI, other NCI staff, and NIAID colleagues for assisting in conceptualizing the Network.

Questions and Answers

Dr. Anna D. Barker, Chief Strategy Officer, Lawrence J. Ellison Institute for Transformative Medicine, University of Southern California, queried whether the aim of the RFP is to attract scientists from the infectious diseases research community, the cancer research community, or both. Because the SeroNet is a collaborative effort with the NIAID, Dr. Lowy clarified that the NCI anticipates that both groups would respond to the RFP, especially researchers with expertise in this area.

Recalling that many NCI-supported investigators switched research platforms to study HIV during that initial crisis, Dr. Barker queried whether the NCI had considered tracking NCI-funded investigators who may decide to focus on infectious diseases amid this and future pandemics. Dr. Lowy noted that tracking such occurrences could be considered.

Dr. Bar-Sagi asked about efforts to gain information on parallel serology initiatives in Cancer Centers across the Nation to reduce the likelihood of allotting resources to smaller and statistically underpowered studies. Dr. Lowy responded that the NCI, through the NIAID, is kept up-to-date on similar initiatives, particularly via workshops the NIAID convenes.

V. NCI-SUPPORTED CLINICAL RESEARCH DURING THE COVID-19 PANDEMIC— DR. JAMES H. DOROSHOW

Dr. James H. Doroshow, Deputy Director for Clinical and Translational Research, and Director, Division of Cancer Treatment and Diagnosis (DCTD), provided an update on the NCCAPS and the IRP's clinical trial evaluating acalabrutinib, a Bruton tyrosine kinase inhibitor, in hospitalized patients with severe COVID-19. Dr. Doroshow briefly noted that the tocilizumab (Genentech, Inc.) compassionate use clinical trial has been approved by the NCI central institutional review board (CIRB). He noted that the aim is to open the trial at clinical sites nationwide that have limited access to tocilizumab and in underresourced settings. Updates will be provided at a future meeting.

Dr. Doroshow remarked on the challenges of conducting clinical research during a pandemic and elaborated on several operational impediments to clinical cancer research, such as decreased efficiency because of physical distancing, limited outpatient clinical and inpatient resources, reduced investigational pharmacy staffing, and suspended translational research laboratory activities. In the NCTN trials, the accrual rates decreased more than 40 percent beginning mid-March 2020 for all trials (interventional and screening) and across all cooperative groups. Recent reports as of 12 June 2020 indicate that patient accruals are beginning to increase for some screening trials.

On 21 May 2020, the NCI activated NCCAPS, a longitudinal COVID-19 natural history study being led by IRP investigator, Dr. Larissa Korde, and Vanderbilt University Medical Center investigator, Dr. Brian Rini. The aims are to improve understanding into how COVID-19-disrupted cancer therapy could potentially lead to worse outcomes for patients and gain insight into the long-term outcomes of cancer patients with COVID-19. Discussing the rationale for such a trial, Dr. Doroshow explained that recent large-scale COVID-19 studies show that cancer patients are hospitalized and require mechanical ventilation more frequently than people who do not have cancer. A new report from the Vanderbilt-Ingram Cancer Center–led COVID-19 and Cancer Consortium revealed a 30-day mortality rate of 13 percent in cancer patients. The NCCAPS goals are to: 1) enroll a large cohort of patients being treated for cancer who also test positive for SARS-CoV-2 to characterize factors that correlate with COVID-19 severity; 2) describe modifications to cancer treatment made because of COVID-19 and evaluate the association of COVID-19 with cancer outcomes specific to certain clinical and pathological histologies; and, 3) assess anti-SARS-CoV-2 antibody development, cytokine abnormalities, and genetic polymorphisms related to severe COVID-19.

The objective is to create a biobank of clinical data, research blood specimens, and radiological images for future research. The study opened across the NCTN, Early Therapeutic Clinical Trials Network (ETCTN), and NCI Community Oncology Research Program (NCORP) sites. In the NCCAPS schema, patients being tested for SARS-CoV-2 are checked in/preregistered (Step 0) and have their baseline data collected. Patients testing positive are registered (Step 1), become enrolled, and have their data and biospecimens collected. Positive test results may occur no earlier than 14 days prior to Step 1 registration. The Step 1 planned accrual is 2,000 patients, and the objective is to follow patient outcomes for 2 years. Modifications to the NCI clinical trial processes to enable opening NCCAPS at the participating NCTN, ETCTN, and NCORP sites include allowing remote informed consent, eliminating the need for extra site visits, and temporarily relaxing the requirement for onsite processing of research blood samples. After enrolling adult patients for 1 month, the next steps will be to request a protocol amendment to begin enrolling pediatric patients, add quality-of-life assessments, and incorporate guidelines for imaging analysis. As of 2 June 2020, 220 sites had registered for the study, and on 5 June 2020, the first patient was enrolled.

Dr. Doroshov reported that the CCR, in a study led by Drs. Mark Roschewski, Louis M. Staudt, and Wyndham H. Wilson, published findings in the 5 June 2020 issue of *Science Immunology* on the off-label use of acalabrutinib in hospitalized patients with severe COVID-19. A hyperinflammatory lung is a characteristic feature of severe COVID-19, and the researchers evaluated whether the anti-cancer agent acalabrutinib could block this inflammation and reduce the need for a ventilator and prevent death. A total of 19 severe COVID-19 patients (11 on supplemental oxygen and 8 intubated or on a ventilator) across five U.S. clinical sites were enrolled in the study and treated for 10 to 14 days with acalabrutinib. The results showed that acalabrutinib treatment improved oxygenation in 9 of 11 patients, decreased inflammatory biomarkers, and led to extubating four of eight patients.

Questions and Answers

Dr. Andrea A. Hayes-Jordan, Byah Thompson Doxey Distinguished Professor of Surgery, Division Chief, Pediatric Surgery, Surgeon-in-Chief, The University of North Carolina Children's Hospital, suggested expanding the eligibility criteria regarding pediatric enrollment in the NCCAPS to include newborn patients.

Dr. David A. Tuveson, Roy J. Zuckerman Professor, Director of the Cancer Center, Cold Spring Harbor Laboratory, suggested exploring adaptive trial designs, similar to the Molecular Analysis for Therapy Choice (MATCH) Trial, in which patients enrolled in existing Cancer Center COVID-19 trials can be considered for the NCCAPS.

Dr. Cheryl L. Willman, The Maurice and Margaret Liberman Distinguished Endowed Chair in Cancer Research, University of New Mexico (UNM) Distinguished Professor of Pathology, UNM School of Medicine, Director and CEO, UNM Comprehensive Cancer Center, UNM, requested revisiting the eligibility criteria concerning patients who have tested positive for SARS-CoV-2 no more than 14 days prior to enrollment in the NCCAPS, particularly for increasing accrual of underrepresented minority patients.

VI. MINORITY ACCRUAL TO NCI NATIONAL CLINICAL TRIALS NETWORK (NCTN) AND NCI COMMUNITY ONCOLOGY RESEARCH PROGRAM (NCORP) CLINICAL TRIALS—DR. WORTA MCCASKILL-STEVENS

Dr. Wortá McCaskill-Stevens, Chief, Community Oncology and Prevention Trials Research Group, DCP, presented the results of an analysis, a 20-year review, to inform strategies for the enrollment of individuals from diverse populations in NCI clinical trials. Dr. McCaskill-Stevens discussed minority accrual from 1999 to 2019 and reported results using the Office of Management and Budget (OMB) categories on race and ethnicity. The Cancer Therapy Evaluation Program (CTEP) Enterprise System was

used for the analysis. Data from the Cooperative Groups/NCI's **National Clinical Trials Network (NCTN) and the NCORP were analyzed, and figures were reported in 3-year intervals.**

From 1999 to 2019, minority accrual in NCTN and NCORP clinical trials increased from 14 percent to 25 percent, or 19 percent overall. Additionally, accrual of Black/African American participants increased from 8 to 11 percent, or 9 percent overall. For Black/African American participants, the most common age groups were 40 to 64 years and 65 to 69 years. Dr. McCaskill-Stevens noted that older Black/African American individuals (i.e., 70 years of age or older) were underrepresented. Accrual of Hispanic or Latino participants from 1999 to 2019 increased from 4 percent to 10 percent, or 7 percent overall. The percentage of younger Hispanic or Latino participants (i.e., birth to 14 years of age) was large, relative to that of younger Black/African American participants. Accrual of other groups was as follows: Asian (3%), American Indian or Alaska Native (0.5%), Native Hawaiian or Other Pacific Islander (0.3%), and more than one race (0.2%).

The analysis also included NCORP accrual to NCI's NCTN clinical trials from 1999 to 2019. The contribution of minority enrollment was 27 percent. Dr. McCaskill-Stevens noted that NCORP supports a specific component dedicated to minority and underserved populations. Additionally, cancer care delivery research revealed insight on factors that influence the enrollment of underserved populations. In highlighting two immuno-oncology trials, EA8143 (renal cell carcinoma) and S1418 (triple receptor-negative breast cancer), Dr. McCaskill-Stevens reported that overall minority accruals of 20.6 percent and 28.3 percent, respectively.

Dr. McCaskill-Stevens emphasized the importance of disaggregation within race and ethnicity. She noted that future research on country of origin might inform strategies for enrollment. A clinical trial log will allow the expansion of demographic information, which might be used to inform trial design. Additionally, inclusion of accruals for tissue acquisition studies, quality-of-life studies, and translation of patient-reported outcomes are of particular importance. Also, there is the need to identify strategies to improve enrollment of other underrepresented groups (e.g., elderly individuals, adolescents and young adults, and sexual and gender minorities).

Questions and Answers

In response to a question from Dr. Victoria Seewaldt, Ruth Ziegler Professor, Chair, Department of Population Sciences, Beckman Research Institute, City of Hope, Dr. McCaskill-Stevens confirmed that the group has included genetic admixture studies in the analysis.

Dr. Robert Vonderheide, John H. Glick MD Abramson Cancer Center's Professor, Professor of Medicine, Perelman School of Medicine, Director, Abramson Cancer Center, University of Pennsylvania, asked how much more work is needed in terms of enrollment. Dr. McCaskill-Stevens emphasized the importance of enabling access in areas of high concentration and providing outreach to highly impacted populations. Dr. Vonderheide indicated that access to community health systems, as well as access to care within cancer centers are also barriers to enrollment.

Dr. Willman noted that eligibility criteria for trials regarding comorbid conditions often present a barrier to access. Additionally, she spoke on the importance of launching trials in high-incidence populations. Dr. McCaskill-Stevens suggested partnerships between primary care physicians and oncologists. Dr. Willman added that many patients do not have a primary care provider.

Dr. Otis Brawley, Bloomberg Distinguished Professor of Oncology and Epidemiology, The Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University, suggested conducting focused studies on groups of individuals who are at high risk for a particular cancer, as opposed to conducting trials based solely on geographic region. He noted that disease prevalence might be higher in this group

than in the national aggregated data and emphasized the importance of directing resources to the community. Dr. McCaskill-Stevens agreed and reiterated the importance of considering country of origin.

Dr. Ian Thompson, President, CHRISTUS Santa Rosa Medical Center Hospital, Texas Urology Group, pointed out that demographic characterization can vary across reports.

VII. BSA CHILDHOOD CANCER DATA INITIATIVE *AD HOC* WORKING GROUP REPORT—DRS. OTIS W. BRAWLEY AND KEVIN M. SHANNON

Dr. Brawley presented the BSA Childhood Cancer Data Initiative (CCDI) Working Group report on data sharing opportunities in childhood and adolescent and young adult (AYA) cancer research. He recognized the Working Group members and Co-Chair Dr. Kevin M. Shannon, American Cancer Society Research Professor, Auerback Distinguished Professor of Molecular Oncology, Professor, Department of Pediatrics, School of Medicine, University of California, San Francisco. Dr. Brawley informed members that the Working Group was convened on 25 November 2019 by Drs. Sharpless and Lowy and was charged to provide general guidance related to the development and implementation of the CCDI, establish more efficient ways to share and use childhood cancer data, and identify novel therapeutic targets and approaches to enable new research pursuits to better understand the biology of childhood cancers.

The BSA and NCAB members were reminded that Congress appropriated \$500 M for childhood cancer, to be allocated over 10 years. The purpose is to support the broader pediatric cancer community's goal of maximizing the benefits of data by learning from every patient so that, ultimately, those patients, survivors, and their families can benefit. The funding for the CCDI began with the FY 2020 appropriation of \$50 M allocated to the NCI. NCI's CCDI goals are to maximize every opportunity to improve treatments and outcomes for children with cancer; build a connected data infrastructure to enable childhood cancer data sharing from multiple sources; identify opportunities to improve the effect of data for patients, clinicians, and researchers; and develop and enhance tools and methods to extract knowledge from data. The CCDI complements other NCI childhood and AYA cancer initiatives by optimizing data sharing and connecting data from basic research, population studies, real-world patient data, preclinical models, biospecimen repositories, and clinical trials.

Dr. Brawley noted that after their initial meeting, the Working Group met via a conference call to discuss the key focus areas for the CCDI and identify priority topics and goals. At the 27 March 2020 and 31 March 2020 virtual meetings, the NCI provided an overview of existing pediatric AYA efforts and their relationship to the CCDI, and the Working Group established consensus on the priority areas of the recommendations and generated a roadmap for compiling the report. In a subsequent series of meetings, the Working Group continued deliberations to develop and finalize the recommendations and write the final report.

Dr. Brawley summarized the Working Group recommendations across seven broad thematic areas in pediatric and AYA research:

Types of Data for Collection and Aggregation. Aggregate six broad categories of data, including clinical, treatment, and outcome data; molecular data; archived biospecimen data; longitudinal population data; patient-derived xenograft and genetically engineered mouse models data; and existing preclinical data. Aggregate data from prior molecular analysis of pediatric/AYA cancers. Implement strategies to make all CCDI data representative of the full spectrum of pediatric/AYA cancer patients in the United States. Include plans to incorporate knowledge gained during the 10-year CCDI effort into the Initiative's evolution.

Landscape of Pediatric/AYA Cancer Research Data and Needs Analysis. Convene experts to develop consensus guidelines addressing clinical and molecular characterization and sample archiving

needs for each pediatric and AYA cancer diagnosis. Perform a comprehensive inventory of data, databases, and shared research infrastructures, assessing each for quality, relevance, and integration feasibility. Collect and integrate new “ideal” data types prospectively, on every newly diagnosed patient. Consider ways to collect off-trial patient clinical data. Review current practices for collecting and characterizing biospecimens and assigning unique and privacy-preserving identifiers. Develop the National Childhood Cancer Registry (NCCR) as a national resource for aggregating and accessing high-quality curated data. Convene a broad spectrum of subject-matter experts and stakeholders with expertise in technology, data science, disease biology, and clinical care to assist with the architecture design and road-mapping of the NCCR and CCDI. Include activities focused on generating and aggregating preclinical data and developing infrastructure tools that will enhance translation.

Potential Barriers to Progress. Commit to support ongoing data sharing over time through policy and funding. Consider multiple, creative ways to engage with and utilize expertise from a wide variety of stakeholders in the pediatric and AYA cancer survivor communities. Consider committing resources to consent, sequence samples from, and retain diverse populations in the CCDI database.

Generating New Data. Seek ways to support the generation of evidence needed to change outcomes in pediatric cancer. Harmonize terminologies and coding between cancer research and clinical care data as recommended in the NCAB *ad hoc* Working Group on Data Science June 2019 report. Apply machine-learning approaches to analyze data from electronic health records. Remove barriers to data access for the broader community by supporting the creation of data resources that simplify data access.

Distinction Between Research and Clinical Data. Set clear expectations regarding the need for broad data-sharing policies governing all CCDI activities. Explore barcoding approaches to data and metadata from individual patient data so that uniqueness can be assured. Develop a long-term strategy for tracking pediatric and AYA cancer patients over many decades across their lifespan.

Engaging Diverse Stakeholders for Input. Consider multiple, creative ways to engage with and utilize expertise from a wide variety of stakeholders in the pediatric and AYA cancer survivor communities. Explore creative ways for parents to opt in to sharing (de-identified) data collected on their child. Consider developing the CCDI’s infrastructure in a way that allows patients and families to see and share their data.

Opportunities for Transformative Discoveries. Develop a national strategy to offer appropriate biospecimen collection and genomic testing to every pediatric/AYA patient with cancer within 2 years. Aggregate data from existing cell lines, patient-derived xenografts, and genetically engineered mouse models of pediatric/AYA cancers to inform rapid pediatric translation in accordance with the Research to Accelerate Cures and Equity for Children (RACE) Act. Identify patients who have a remarkable initial response to conventional chemotherapy and/or targeted therapies. Improve biobanking efforts at intake by adding quality control, digital image generation, and nucleic acid extraction for all children diagnosed with specific solid tumors. Consider a focused biologic effort to delineate the molecular landscapes of specific rare cancers and leverage the Children’s Oncology Group’s (COG) biorepository and other archived biospecimens.

Questions and Answers

The BSA and NCAB members commended the Working Group for its report and inquired about incentives for private foundations to share data in the CCDI, particularly those engaging with NCI-supported programs (e.g., COG). Dr. Brawley explained that providing incentives to private corporations would likely be more challenging than for the universities, but he could not address today how the NCI would consider incentivizing data sharing for the CCDI. Dr. Shannon called attention to the optimistic model of funding sequencing for adult cancers, American Association for Cancer Research Project

Genomics Evidence Neoplasia Information Exchange (commonly called GENIE), which the CCDI could emulate for pediatric cancers.

Dr. Leslie L. Robison, Chairman, Department of Epidemiology and Cancer Control, St. Jude Children's Research Hospital, Associate Director, St. Jude Comprehensive Cancer Center emphasized data quality as a priority for the CCDI and remarked on the level of investment, infrastructure, and monitoring required to collect, generate, and evaluate high-quality data prior to those data being shared.

Dr. Timothy J. Ley, Professor of Medicine and Genetics, Division of Oncology, Department of Medicine, Washington University School of Medicine in St. Louis, encouraged the NCI to establish whole-genome sequencing (WGS) as the standard genomic data for pediatric cancer patients, because WES has been the most stable of the existing platforms.

Motion. A motion to accept the final report of the BSA *ad hoc* Working Group to Support the CCDI was approved unanimously.

VIII. RFA/COOP. AGR./RFP AND PAR CONCEPTS—NEW AND RE-ISSUE—NCI PROGRAM STAFF

Division of Cancer Control and Population Sciences

New Cohorts to Assess Environmental Exposures and Cancer Risk (New RFA)— Dr. Somdat Mahabir

Dr. Somdat Mahabir, Program Director, Environmental Epidemiology Branch, Epidemiology and Genomics Research Program, DCCPS, presented a new RFA concept to establish new cancer etiology cohorts to assess environmental exposures and cancer risk. Dr. Mahabir informed members that the RFA aligns with the recommendations of the NCAB *ad hoc* Working Group on Strategic Approaches and Opportunities in Population Science, Epidemiology, and Disparities in its final report on the NCI extramural cancer epidemiology cohort studies.

Dr. Mahabir explained that environmental exposures, such as emerging new exposures, persistent chemicals (e.g., polyfluorinated alkyl substances and endocrine disrupting chemicals), and chemical mixtures, are understudied. Although the International Agency for Research on Cancer (IARC) and the U.S. National Toxicology Program (NTP) both have identified several known carcinogens to humans, environmental exposures lack adequate evidence to properly classify carcinogens. Prospective study designs are needed to better determine the key carcinogenic hallmarks of environmental exposures. He noted that the challenge with the existing etiology cohorts, including the Agricultural Health Study and the U.S. Radiologic Technologists, is that they were formed in the 1980s and are aging, and the current resources are limited in their abilities to address new and emerging environmental exposures. Furthermore, the existing cohorts lack adequate representation of racial/ethnic populations.

The purpose of this RFA is to sponsor new cancer etiology cohorts that utilize innovative strategies and approaches to address environmental exposures, genetics, and cancer etiological knowledge gaps across diverse populations and to ensure rigor and reproducibility of data and biospecimen collections. The RFA will support the establishment of five new cohorts, facilitating a coordinating center, and developing common data elements and biospecimen collection.

Subcommittee Review. Dr. Melissa L. Bondy, Chair and Professor, Department of Epidemiology and Population Health, Co-Director, Center for Population Health Sciences, Associate Director for Population Sciences, Stanford Cancer Institute, expressed the Subcommittee's support for the concept, which addresses a gap in knowledge on environmental exposures and cancer. Dr. Bondy indicated that the Subcommittee strongly supports increasing diversity in the NCI etiology cohorts to include underrepresented populations and encourages uniform biobanking protocols, biospecimen annotation, and standardized data collection across the new cohorts. The Subcommittee appreciated the NCI staff responses to their suggestions on emphasizing innovative strategies and rigor and reproducibility on biospecimen and data collection.

The first-year cost for the one-time issuance is estimated at \$6.5 M for five UG3/UH3 awards for Years 1 and 2 and \$12.5 M for Years 3–6, with a total cost of \$63 M for 6 years.

Questions and Answers

Dr. Tuveson suggested including in the RFA the requirement to collect microbiome samples to assess effects of potential bacteria-related carcinogens, given that *Escherichia coli* itself creates carcinogens and has been linked to colorectal cancers.

Motion. A motion to approve the Division of Cancer Control and Population Sciences' new RFA entitled "New Cohorts to Assess Environmental Exposures and Cancer Risk" was approved with 22 ayes, 1 nay, and 1 abstention.

Division of Cancer Treatment and Diagnosis

Childhood Cancer Survivorship Study (CCSS) (Re-Issue RFA)—Dr. Nita Seibel

Dr. Nita Seibel, Head, Pediatric Solid Tumor Therapeutics, Clinical Investigations Branch, CTEP, DCTD, presented a re-issue RFA concept to continue the CCSS, an open resource for cancer survivorship studies. Dr. Seibel indicated that the CCSS is composed of a retrospective longitudinal cohort of pediatric and adolescent cancer survivors (English and Spanish speaking) diagnosed with leukemia, lymphoma, central nervous system tumors, Wilms tumor, neuroblastoma, or sarcomas (soft-tissue or bone) between 1970 and 1999. A total of 37,593 eligible 5-year survivors, all younger than 21 years of age at diagnosis, can be evaluated for late mortality studies. Of the 37,593 participants, 25,664 were diagnosed between 1970 and 1986 and 11,000 between 1987 and 1999. More than 5,000 siblings are participating in the study as the control group. Detailed treatment data and biospecimens are collected, all publicly available to researchers.

Regarding accomplishments and impact, Dr. Seibel informed members that more than 700 CCSS investigators, including 80 trainees, have generated 367 publications resulting from 54 investigator-initiated studies, totaling \$53.1 M in grant funding. The CCSS publications continue to inform COG's late effects guidelines, particularly concerning radiation and cancer experience late effects. The International Guideline Harmonization Group also has referenced CCSS publications in its recommendations. She also highlighted some of the recent CCSS findings on the overall survival following solid organ transplantation, risk-reducing interventions in breast cancer, and intervention trials, as well as new opportunities for the CCSS, including initiating the CCSS Vanguard Cohort consisting of survivors diagnosed between 2000 and 2020 who received novel therapies as part of standard therapy or protocols.

This RFA re-issuance will support expanding the CCSS cohort in new areas, such as, neurocognitive/physiologic aging, mechanisms of aging, and health services research, as well as developing and testing clinical models for precision prevention, and continuing to develop and support intervention studies utilizing new approaches.

Subcommittee Review. Dr. Shannon expressed the Subcommittee’s support for the re-issuance concept, noting the link to the CCDI. He remarked on the success the CCSS to reduce the burden for childhood cancer survivors. The Subcommittee emphasized ensuring access to the CCSS for established as well as new investigators and fast-tracking proposals for researchers with established statistical support.

The first-year cost for the one-time issuance is estimated at \$2.74 M for one U24 award, with a total cost of \$13.7 M for 5 years.

Motion. A motion to concur on the Division of Cancer Treatment and Diagnosis’ (DCTD) re-issue RFA entitled “Childhood Cancer Survivorship Study (CCSS)” was approved with 22 ayes, zero nays, and 2 abstentions.

Clinical Trials Monitoring Service (CTMS) (New RFP)—Mr. Gary L. Smith

Mr. Gary L. Smith, Branch Chief, Clinical Trials Monitoring Branch, CTEP, DCTD, presented a new RFP concept for the CTMS research support contract. Mr. Smith informed members that CTMS provides infrastructure and core services (e.g., data management, quality assurance, and monitoring) for the ETCTN and other early-phase clinical trials. He noted that it also ensures protection of human subjects; collection of high-quality clinical data; and compliance with HHS, NCI, FDA, and good clinical practice requirements. For the ETCTN, the CTMS is responsible for providing a centralized patient registration system, a patient data capture protocol using Medidata Rave®, and a systematic process for data quality-control reviews. The CTMS also 1) coordinates the Data Safety Monitoring Board for randomized studies, 2) displays key data items in Web Reporting for review by the Investigational Drug Branch Medical Officer, 3) provides oversight for all CTEP investigational new drug ETCTN and NCTN studies, and 4) conducts onsite audits and co-site visits to ensure compliance in clinical trials.

Mr. Smith noted that the ETCTN, which consists of eight lead academic organizations, 45 affiliated organizations, and 15 Experimental Drug Development Opportunities Programs, has had several accomplishments in the recent contract year. Specifically, the CTMS staff built 30 new studies in Medidata Rave, implemented 47 new electronic case report forms, processed 359 protocol amendments, and enrolled 1,148 patients in ETCTN trials. In addition, CTMS staff conducted 59 annual site visits, performed 68 data audits, and reviewed 1,070 patient cases. Over the past 3 years, the CTMS assisted the ETCTN in conducting 40 Phase I, 8 Phase I/II, 24 Phase II, and 8 randomized trials. The RFP will support the contract recomplete and continue the CTMS activities.

Subcommittee Review. Dr. W. Kimryn Rathmell, Cornelius A. Craig Professor, Department of Medicine, Director, Division of Hematology and Oncology, Vanderbilt University Medical Center, expressed the Subcommittee’s strong enthusiasm for the concept, which has been a productive program of the NCI. Dr. Rathmell noted that the Subcommittee encourages the NCI to investigate establishing a remote platform in the CTMS to ensure that activities are not impeded in situations similar to the COVID-19 pandemic and, if approved, incorporate the platform into the CTMS RFP.

The first-year cost for the one-time issuance is estimated at \$8.1 M for a 1-year contract, with a total cost of \$88.8 M for 9 option years.

Motion. A motion to approve the DCTD’s new RFP entitled “Clinical Trials Monitoring Service (CTMS)” was approved unanimously.

Office of the Director

Collaborative Approaches to Engineer Biology for Cancer Applications (New RFA/Coop. Agr.)—Dr. Michelle Berny-Lang

Dr. Michelle Berny-Lang, Program Director, Center for Strategic Scientific Initiatives (CSSI), Office of the Director, introduced a new RFA/Coop. Agr. concept on developing collaborative approaches to engineer biology for cancer applications, which is a joint NCI and National Institute of Biomedical Imaging and Bioengineering (NIBIB) effort. Dr. Berny-Lang explained that the CSSI defines synthetic biology as the design, construction, and characterization of improved or novel biological systems using engineering design principles. The opportunities to engineer biology for cancer have been enabled by advances in cellular and molecular engineering and computation.

The NCI–NIBIB collaboration merges technology development (engineers) with cancer research needs (cancer researchers) and leverages the existing NIBIB and NIH synthetic biology investments and research portfolios. During the 2019 NIH Synthetic Biology Consortium Annual Meeting, participants identified cancer challenges amenable to synthetic biology approaches, but highlighted gaps between the cancer and synthetic biology communities. The goal of this RFA is to stimulate collaborations between engineers and cancer researchers to expand the use of synthetic biology to advance understanding and management of cancer. The RFA will also establish a Synthetic Biology Technology Consortium and will support advanced development toward context of use that will fit within the NIBIB technology development pipeline.

Subcommittee Review. Dr. Sylvia Plevritis, Chair, Department of Biomedical Data Science, Professor, Department of Biomedical Data Science and Radiology, Stanford University School of Medicine, expressed the Subcommittee’s enthusiasm and support for the concept.

The first-year cost for the one-time issuance is estimated at \$4.2 M for four to six U01 awards, with a total cost of \$21 M for 5 years.

Motion. A motion to approve the Office of the Director’s (OD) new RFA/Coop. Agr. entitled “Collaborative Approaches to Engineer Biology for Cancer Applications” was approved unanimously.

The NCI Predoctoral to Postdoctoral Fellow Transition Award (F99/K00) (Re-Issue RFA)—Dr. Oliver Bogler

Dr. Oliver Bogler, Director, Center for Cancer Training (CCT), presented a re-issue RFA concept of the NCI predoctoral (F99) to postdoctoral fellow (K00) transition award, which demonstrates NCI’s commitment to this career phase. Dr. Bogler noted the disparity between the number of predoctoral trainees and the number of independent investigator positions. In fact, the number of students receiving a doctoral degree within the past 30 years has doubled and the number of postdoctoral fellows tripled, but the number of independent investigator awards was not increasing to match this pace. With 43 years being the average age when Ph.D. principal investigators receive their first R01, the most talented individuals have been pursuing careers outside of academic research. Thus, the NCI established the F99/K00 transition award in 2015 to enable graduate students nearing the completion of their programs to transition to postdoctoral studies.

Dr. Bolger informed members that the objectives of the RFA are twofold, i.e., to: 1) demonstrate that a cancer research career is rewarding, valuable, and viable and 2) identify the best and brightest candidates. The aim is to engage and retain emerging scientists in the cancer research community early, facilitate their joining leading laboratories in the cancer field, and position them for applying for a F99/K00 award. The RFA provides up to 6 years of support - 2 years of predoctoral work and 4 years of

postdoctoral training. The award is portable and allows the grantees the flexibility of choosing their own postdoctoral training opportunities. One F99/K00 application per academic institution is allowed annually, and mentors must hold an R01-equivalent grant. The F99 applications are reviewed and approved in the NCI regular study section process, which evaluates the excellence of the applicants, their academic and publication records, and recommendation letters. A list of accomplishments and description of the research accompany the application. For the K00 transition and postdoctoral phase, the grantees submit a research proposal consisting of a short research description of their postdoctoral training and their proposed mentor's support. Successful applications are approved by the CCT program director.

From FY 2016 to FY 2019, the NCI trained four cohorts and issued 112 F99/K00 awards across 68 institutions spanning 54 congressional districts. The fifth cohort awarded is soon to be announced. For F99/K00 Cohorts 1 and 2, 100 percent completed graduate work, and the majority (89 to 91%) transitioned to postdoctoral positions, of whom 85 percent received training at the Cancer Centers. Most of the research proposals across cohorts have been cancer-focused and have resulted in 226 publications. This RFA re-issuance will support the next series of cohorts (Cohorts 5–10) consisting of 24 applications per group.

Subcommittee Review. Dr. Michelle M. Le Beau, Arthur and Marian Edelstein Professor of Medicine, Director, University of Chicago Comprehensive Cancer Center, The University of Chicago, expressed the Subcommittee's strong support for the re-issuance concept, which is supporting a program unique to the NCI. Dr. Le Beau remarked on how the NCI F99/K00 program enriches the cancer research field and attracts the best candidates. The Subcommittee suggested that the NCI provide opportunities for graduate students enrolled in a physician-scientist program to participate in a parallel funding mechanism.

The first-year cost for the one-time issuance is estimated at \$11 M for 24 awards, with a total cost of \$55 M for 5 years.

Questions and Answers

Dr. Ali-Osman remarked on how the F99/K00 program provides an opportunity to address workforce diversity and increase underrepresented minority participation in cancer research. Dr. Bogler explained that the NIH Scientific Workforce Diversity Office informs the NCI of any next steps in this area and noted that the CCT also welcomes input from the Boards on this topic. Dr. Shannon added that the NCI could consider having institutions nominate two applicants, provided that one candidate is an underrepresented minority.

BSA Chair Dr. Bar-Sagi asked whether the NCI has considered the impact of the delays in career trajectories for trainees because of COVID-19, especially for achieving research milestones. Dr. Bogler responded that the CCT is communicating any updates and addressing frequently asked questions for the cancer research community via the NCI blog. He conveyed that the NCI is providing maximum flexibility to accommodate delays affecting careers and/or deadlines, including allowing extensions on the F99/K00 applications.

Motion. A motion to concur on the OD's re-issue RFA entitled "The NCI Predoctoral to Postdoctoral Fellow Transition Award (F99/K00)" was approved unanimously.

Small Business Transition Grant (New RFA)—Dr. Kory Hallett

Dr. Kory Hallett, Program Director, Small Business Innovation Research (SBIR) Development Center, NCI, introduced a new RFA concept on a small business transition grant, which is an entrepreneurial training grant modeled after the NIH Pathway to Independence Award (K99/R00). Dr. Hallett noted that the NCI SBIR/Small Business Technology Transfer (STTR) portfolio reveals that early- to mid-career-level scientists often transition to entrepreneurship but have no grant similar K99 to support

such a shift. The SBIR/STTR programs are congressionally mandated and support commercial research by small businesses and are not designed to support a scientist-to-entrepreneur transition.

An NCI SBIR/STTR portfolio analysis showed that from FY 2017 to FY 2019, experienced NIH investigators who had received an R01 or an equivalent grant and were 5 to 10 years past earning a terminal degree had the highest SBIR/STTR Phase II award success rate. The SBIR Development Center solicited feedback from academic innovation offices at 62 of the 70 Cancer Centers and their serving institutions; responses indicate that postdoctoral fellows are moving from academia to a small business setting with the technologies they develop. This RFA will be a 2-year pilot and will be structured into stages: Phase I STTR, which supports the postdoctoral fellow as a principal investigator training and preparing the technology; Transition, a fast-track, during which the principal investigator moves to the small business and updates the technology; and Phase II SBIR, the business team phase, when the principal investigator is nontransferable. The RFA will support emerging entrepreneurs who are no more than 8 years past a terminal degree. Applications must include milestones and go/no-go criteria for the fast-track transition.

Subcommittee Review. Dr. David Sidransky, Director, Head and Neck Cancer Research, Professor of Otolaryngology–Head and Neck Surgery, Department of Otolaryngology–Head and Neck Surgery, Johns Hopkins University School of Medicine, expressed the Subcommittee’s enthusiasm and strong support for the concept. Dr. Sidransky emphasized that not every scientist trained in a laboratory will become a faculty member at an academic or research institution and secure long-term funding. The Small Business Transition Grant provides opportunities for postdoctoral fellows, as principal investigators, to champion their technologies forward to commercialization. The Subcommittee appreciated the NCI staff responding to their questions on the intent of the concept and the extent of mentoring for the awardees.

The first-year cost is estimated at \$2 M for five to seven awards, with a total cost of \$4 M for 2 years.

Questions and Answers

Dr. Max S. Wicha, Madeline and Sidney Forbes Professor of Oncology, Director, Forbes Institute for Cancer Discovery, Founding Director Emeritus, University of Michigan Rogel Cancer Center, Professor of Internal Medicine, Division of Hematology and Oncology, University of Michigan, commented on the need for geographic diversity in the awards, particularly in areas that have levels of NCI funding and venture capital investments. Dr. Wicha also asked whether U.S. citizenship would be a requirement. Dr. Hallett explained that the NCI SBIR Development Center reached out to the Institutional Development Award (IDeA) participants for their input on developing this program. She noted that the congressionally mandated SBIR/STTR program has strict requirements that those funds support U.S. business, with few exceptions.

Dr. Hayes-Jordan sought clarity on how the NCI is supporting postdoctoral fellows leaving academia to start a business. Dr. Hallett clarified that the NCI is not recruiting postdoctoral fellows to start businesses. The RFA would appeal to those already planning to transition to a small business, but will only support a small number of awards (e.g., 5 to 7) in a 2-year pilot.

Dr. Howard J. Fingert, Consultant, commented on this new program as an organized approach to assist those interested in transitioning from academia to industry. He indicated that successful recipients of this award could share their knowledge and any best practices from the 2-year pilot that might inform changes in the future.

Motion. A motion to approve the OD’s new RFA entitled “Small Business Transition Grant” was approved unanimously.

The Cancer Genome Atlas (TCGA) Network: TCGA Genome Characterization (GCCs) and TCGA Genome Data Analysis Centers (GDACs) (Re-Issue RFA/Coop. Agr.) — Dr. Jean Claude Zenklusen

Dr. Jean Claude Zenklusen, Director, The Cancer Genome Atlas (TCGA), Center for Cancer Genomics (CCG), presented a re-issue RFA/Coop. Agr. concept of the TCGA Network (renamed Genomics Data Analysis Network [GDAN]), which is an extension of the TCGA Genome Characterization Center (GCC) and Genome Data Analysis Center (GDAC). Dr. Zenklusen informed members that insight gained from the TCGA emphasized the need for: 1) for high-quality molecular analytes, 2) experiments performed using strict standardized protocols, and 3) results deposited in structured formats to be used by the research community. One unique aspect of the TCGA Project, an integrated research network, is that it has been successful and serves a model for all future CCG-approved large-scale genomics projects. The GDAN, GCC, and GDAC are components of the CCG genome characterization pipeline, which translates data from the tissue source to the research community and supports several NCI projects (e.g., Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials [ALCHEMIST]).

The GDAN has evolved since the previous funding cycle, is composed of specialized cores addressing various core competencies, and has performed data analysis in support of several TCGA publications since 2016. This RFA re-issuance will support the GDAN's continuing its roles as a resource for any NCI genomics projects that uses the genome characterization pipeline and also will support the addition of several new core competencies, including single-cell sequencing, circulating cell-free DNA analysis, circulating tumor DNA, long-read sequence analysis, and special genomics analysis.

Subcommittee Review. Dr. Karen E. Knudsen, Executive Vice President, Oncology Services, Jefferson Health, Enterprise Director, NCI-Designated Sidney Kimmel Cancer Center at Jefferson, Chair and Hilary Koprowski Endowed Professor, Department of Cancer Biology, Thomas Jefferson University, expressed the Subcommittee's support for the re-issuance concept. Dr. Knudsen noted that the GDAN, which has been an extraordinarily successful program and has sustained its impact, with measurable high return on NCI's investment. The Subcommittee welcomed the name change to GDAN.

The first-year cost for the one-time re-issuance is estimated at \$5 M for 10 U24 awards, with a total cost of \$25 M for 5 years.

Motion. A motion to concur on OD's re-issue RFA entitled "The Cancer Genome Atlas (TCGA) Network: TCGA Genome Characterization (GCCs) and TCGA Genome Data Analysis Center (GDACs) Centers" was approved unanimously.

IX. PAR RE-ISSUE CONCEPTS—DR. PAULETTE GRAY

Dr. Paulette S. Gray, Director, DEA, presented 12 re-issue PARs for BSA consideration and noted that the list and a link to each PAR was made available to BSA members prior to the meeting. Dr. Gray reminded the BSA of the NIH policy established in 2019 that requires an open forum discussion and acceptance by an Advisory Council or Board for new and reissue RFAs, RFPs, and PARs. Because of the large volume of PAR re-issues that the NCI has annually, the BSA agreed to review the re-issues as a group, not individually. Thus, the Board should vote to concur or non-concur with the PAR re-issuances listed below:

- Modular R01s in Cancer Control and Population Sciences (PAR-18-869)
- Secondary Analysis and Integration of Existing Data to Elucidate the Genetic Architecture of Cancer Risk and Related Outcomes (PA-17-239, PA-17-243)
- Cancer Prevention and Control Clinical Trials Grants Program (R01-Clinical Trials Required)

(PAR-18-559)

- Specialized Programs of Research Excellence (SPOREs) in Human Cancer for Years 2021 through 2023 (PAR-18-313)
- Innovative Research in Cancer Nanotechnology (PAR-17-240)
- Investigator-Initiated Early Phase Clinical Trials for the Division of Cancer Treatment and Diagnosis Programs (PAR-18-560)
- Assay Development and Screening for Discovery of Chemical Probes, Drugs or Immunomodulators (PAR-17-438)
- Academic-Industrial Partnerships for Translation of Technologies for Cancer Diagnosis and Treatment (PAR-18-530)
- The NCI Transition Career Development Award (PAR-18-466, PAR-18-467)
- Cancer Research Education Grants Program (R25) (PAR-18-476, PAR-18-477)
- Exploratory Grant Award to Promote Workforce Diversity in Basic (PAR-18-478)
- Cancer Research (R21 Clinical Trial Not Allowed) (PAR-18-731)

Motion. A motion to concur on the 12 PAR re-issuances was approved unanimously.

X. RFA/COOP. AGR. CANCER MOONSHOTSM CONCEPT—NEW

Office of the Director

Clinical Translation of Activated Optical Fluorescence Methods and Technologies for Sensitive Cancer Detection *In Vivo* (New PAR)—Dr. Robert J. Nordstrom

Dr. Robert J. Nordstrom, Chief, Image-Guided Intervention Branch, Cancer Imaging Program, DCTD, presented a new PAR on the clinical translation of activated optical fluorescence *in vivo* methods and technologies for sensitive cancer detection. Dr. Nordstrom noted that although liquid biopsy methods can detect a tumor after it reaches a volume of 1 to 2 cubic millimeters (mm³), the clinical imaging techniques (e.g., magnetic resonance imaging or optical imaging) require a volume 1,000 times greater. Bridging this gap in sensitivity for tumor detection has been an ongoing issue in the imaging field. The aim of this PAR is to harness high-sensitivity imaging to locate small-volume cancers. The goal of the project is to demonstrate enhanced sensitivity of imaging that will enable physicians to locate small tumors indicated by fluid-based diagnostic results. Increased imaging sensitivity would be beneficial for early detection of cancers, staging (anatomic) and treatment planning, and detection of residual or metastatic disease. Improved imaging also can reduce patient anxiety.

Members were informed that high-sensitivity imaging of small tumors will require design changes that reduce noise in the system, increase resolving power, and provide a sufficient field of view. Existing clinical imaging modalities can be improved with enhanced contrast agents, targeted probes, and nanoprobes. Thus, the PAR will support a clinically focused study of activated fluorescence to demonstrate tumor imaging sensitivity in line with fluid-based biopsy results. The NCI will seek teams with a proven track record in activated fluorescence research for *in vivo* imaging and will require clinical trial validation.

Subcommittee Review. Dr. Tuveson expressed the Subcommittee's strong support for the concept, which aligns with the Cancer MoonshotSM goals of translating technologies for evaluating disease in humans. Although the project is restricted to the use of optical probes, Dr. Tuveson thinks that this non-invasive technique will have broad application in the clinic and improve care for patients. He indicated that the Subcommittee is enthusiastic about developing better methodologies for staging patients to treatments and for early diagnosis.

Motion. A motion to approve the OD’s new PAR entitled “Clinical Translation of Activated Optical Fluorescence Methods and Technologies for Sensitive Cancer Detection *In Vivo*” was approved unanimously.

XI. ADJOURNMENT OF THE OPEN SESSION—DRS. ELIZABETH M. JAFFEE AND DAFNA BAR-SAGI

Dr. Jaffee adjourned the open session. Only Board members and designated NCI staff remained for the closed session.

XII. NATIONAL CANCER ADVISORY BOARD (NCAB) CLOSED SESSION—DR. ELIZABETH M. JAFFEE

“This portion of the meeting was closed to the public in accordance with the provisions set forth in Sections 552b(c)(4), 552b(c)(6), Title 5 U.S. code, and 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2).”

There was a review of grants and a discussion of personnel and proprietary issues. Members absented themselves from the meeting during discussions for which there was potential conflict of interest, real or apparent.

The Board was informed that a comprehensive listing of all grant applications to be included in the en bloc vote was in the Special Actions package. Those grant applications, as well as those announced during the closed session, could be considered for funding by the Institute.

The NCAB **en bloc** motion to concur with the Initial Review Group (IRG) recommendations was unanimously approved. During the closed session, a total of 2,607 NCI applications were reviewed requesting direct cost support of \$1,007,124,335 and three FDA applications requesting direct cost support of \$364,610.

XIII. ADJOURNMENT—DR. ELIZABETH M. JAFFEE

Dr. Jaffee thanked all the Board members, as well as the visitors and observers, for attending. There being no further business, the 2nd Virtual Joint Meeting of the BSA and NCAB was adjourned at 5:47 p.m. on Monday, 15 June 2020.

<u>8/28/2020</u>	<u>/s/</u>
Date	Dafna Bar-Sagi, Ph.D., Chair, BSA
<u>9/2/2020</u>	<u>/s/</u>
Date	Elizabeth M. Jaffee, M.D., Chair, NCAB
<u>9/2/2020</u>	<u>/s/</u>
Date	Paulette S. Gray, Ph.D., Executive Secretary